

REMARKS/ARGUMENTS

I. STATUS OF THE CLAIMS

With entry of this amendment, claims 1-5, 7, 8, and 10-15 are pending. Claims 1, 5, 7, 10 and 12 are amended, and claims 14 and 15 are new. Support for the amendments and the new claims can be found throughout the specification, drawings, and claims as originally filed.

Claims 1, 5, and 7 are amended to clarify the claim language by replacing the phrase "an amino acid sequence" with "a polypeptide" as suggested by the Examiner. Claims 1, 5, 7, and 12 are further amended to define the abbreviations to LIM, PET, and PSD-95 as requested by the Examiner. These abbreviations are well known in the literature. For example, LIM stands for Lin-11, Isl-1, Mec-3, as evidenced in Bach *et al.* page 5, right col. line 6 (submitted as Exhibit 2 with the response filed on January 30, 2008); PET stands for Prickle Espinas Testin as evidenced in Gubb *et al.* page 2316, left col. line 9 (submitted as Exhibit 3 in the response filed on January 30, 2008); and PSD-95 stands for postsynaptic density-95 as evidenced in Miguad *et al.* page 433 abstract line 4 (submitted as Exhibit 5 in the response filed on January 30, 2008). Claim 10 has been re-written in independent form as suggested by the Examiner.

Claims 14 and 15 are newly added. New claim 14 is directed to the protein fragment of claim 5, wherein the PET domain corresponds to positions 19-89 of the amino acid sequence as shown in SEQ ID NO:1. New claim 15 is directed to the nucleotide chain of claim 7, wherein the PET domain corresponds to position 19-89 of the amino acid sequence as shown in SEQ ID NO:1. New claims 14 and 15 read upon the elected invention drawn to polynucleotides encoding polypeptides, fragments of the encoded polypeptide, vectors, host cells, and methods of recombinant protein production as elected in response to the Restriction Requirement mailed on June 4, 2007. No new matter is added with entry of this amendment.

II. INTERVIEW

Applicant thanks the Examiner for taking the time to conduct the telephone interview on May 28, 2008, to discuss the case. The amendment, Declaration under 37 C.F.R. §1.132 and arguments as presented herein are commensurate with the discussion during the telephone interview.

III. CLAIM OBJECTIONS

Claims 2, 3, and 8 stand rejected as allegedly being in improper multi-dependent form. In particular, claims 2, 3, and 8 depend either directly or indirectly from claim 1 or claim 10, which also depends from claim 1. Applicants thank the Examiner for careful reading of the claims, and note that with entry of this amendment, claim 10 has been re-written in independent form, as suggested by the Examiner.

In view of claim 10 as presently recited, Applicant requests that the Examiner withdraw the objection.

IV. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1, 4, 5, 7, and 10-13 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being vague and indefinite for failure to point out and distinctly claim the subject that the Applicant regards as the invention. In particular, with regard to claims 1, 5, and 7, the Examiner alleges that the phrase "an amino acid sequence that binds PSD-95" is vague and indefinite because a "sequence" is not a material limitation, but rather a characteristic of a molecule, and therefore by itself cannot bind anything.

With regard to claims 1, 5, 7, 12, and 13, the Examiner alleges that the claims are vague and indefinite for reciting the abbreviations "PSD-95", "PET", and "LIM" as limitations. The Examiner alleges that without spelling out the acronyms, or supporting the terms with a SEQ ID NO, a skilled artisan cannot appraise the scope of the claimed subject matter. Furthermore, the Examiner alleges that claims 4, 10, and 11 are indefinite for allegedly being dependent from an indefinite claim.

Applicants have amended claims 1, 5, and 7 to replace the phrase "an amino acid sequence" with "a polypeptide" as suggested by the Examiner. Applicants have also defined the acronyms "PSD-95", "PET" and "LIM" in claims 1, 5, 7, 12, and 13 as requested by the Examiner. As such, Applicants contend that the claims as presently recited are not vague or indefinite, and meet the requirements of 35 U.S.C. §112, second paragraph.

In view of the claims as presently recited, Applicants request that the Examiner withdraw the rejection.

V. REJECTION UNDER 35 U.S.C. §101

Claims 1, 4, 5, 7, and 10-13 stand rejected under 35 U.S.C. §101 as allegedly lacking a specific and substantial credible asserted utility or a well-established utility for the reasons of record as applied to claims 1-5 and 7-8 in section 7 of the Office Action mailed August 30, 2007. Applicant respectfully disagrees.

As stated in the accompanying Declaration of Dr. Masakazu Takeuchi under 37 C.F.R. §1.132, the m-Prickle protein, fragments thereof and nucleic acids as presently claimed do have a specific substantial and credible utility. At the time of the invention, it was well known that the postsynaptic density (PSD) contributes to information processing and the formation of memories by changing synaptic strength in response to neural activity. At the time of the invention, a skilled artisan would readily conclude that proteins associated with the PSD contribute to memory formation. Notably, the inventors have determined that the m-Prickle protein is concentrated in the PSD fraction (see Example 6, and Figure 5 of the specification). Thus, based on this observation, one of skill would conclude that the m-Prickle protein contributes to memory formation (*See*, Declaration, Paragraph 5).

Furthermore, it was also known that PSD-95 at synapses plays a functional role in learning and memory by interacting with other signal molecules. In fact, mutant mice that lacked functional PSD-95 showed a marked inability to learn the position of a hidden platform. It was also well known that PSD-95 forms a complex with the NMDA receptors (NMDA-R), which are known to play a pivotal role in memory formation and learning (*see* Migaud *et al.*, submitted with the response to the Office Action mailed August 30, 2007). Thus, the Declarant concludes that PSD-95 was known to play a functional role in learning (*see* Declaration, Paragraph 6).

The present invention also shows that the m-Prickle protein possesses LIM domains, which are known to function as protein interaction domains, mediating specific contacts between members of functional complexes and modulating the activity of constituent proteins. Based on this observation, the Declarant states that one of skill would recognize that the m-Prickle protein plays a role in learning and memory by interacting with PSD-95 via its LIM domains (*see* Declaration, Paragraph 7).

Even more importantly, the inventors have shown that the m-Prickle protein actually binds to the PSD-95 scaffold complex in the PSD (*see*, page 2, lines 20-21 and page 3, lines 20-22 of the specification). Indeed, the interaction of m-Prickle with the NMDA-R is evidenced by the present inventor's demonstration of the co-precipitation of m-Prickle with the NMDA-R using an anti-m-Prickle antibody (*see* Declaration, Paragraph 8).

The Declarant concludes by stating that, based on understanding in the field at the time of the invention, one of skill would recognize that a protein that is concentrated in the PSD fraction and contains LIM domains known to be associated with protein interaction, such m-Prickle is an adaptor molecule involved in learning and memory. This combined with evidence that m-Prickle actually binds the PSD-95 scaffold complex, establishes that the m-Prickle protein would be a good target for screening for compounds that affect learning and memory.

In light of the Declaration and discussion above, and the asserted specific and substantial credible utility for the proteins and nucleic acids of the invention, Applicants submit that the claimed invention meets the requirements of 35 U.S.C. §101 and request that the Examiner withdraw the rejection.

VI. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Enablement

Claims 1, 4, 5, 7, and 10-13 stand rejected under 35 U.S.C. §112, first paragraph as allegedly not being supported by a specific and substantial credible asserted utility or a well established utility for the reasons set forth above with regard to the rejection under 35 U.S.C. §101, a skilled artisan would not know how to use the claimed invention.

As discussed above in Section V, the present invention is supported by a well established, specific and credible asserted utility. As such, a skilled artisan would understand how to use the invention to practice the well established and credible utility as disclosed in the specification and discussed herein.

In view of the arguments presented herein, Applicants request that the Examiner withdraw the rejection.

Written Description

Claims 5 and 7 stand rejected as allegedly failing to meet the written description requirement. In particular, the Examiner alleges that claims 5 and 7 are directed to fragments of polynucleotides and polypeptides comprising at least eight amino acids "and a PET domain." The Examiner contends that the claims do not require that the fragments possess any particular conserved structure or other disclosed distinguishing feature specifically associated with and being responsible for the "mammalian" protein and the ability of fragment to bind PSD-95. The Examiner contends that the instant specification fails to describe the entire genus of nucleic acids and proteins as claimed. Applicant disagrees.

Claims 5 and 7 are amended to recite "PET (Prickle Espinas Testin)" as requested by the Examiner and therefore the metes and bounds of the PET domain are no longer vague indefinite. Because the PET domain is fully defined in the claim and is supported in the specification as identified in Figure 4, the skilled artisan would readily understand the metes and bounds of the claim.

In addition, Applicant has added new claims 14 and 15, which clearly set forth the boundaries of the PET domain as corresponding to amino acids 19-89 shown in SEQ ID NO1. Therefore, even if a skilled artisan did not readily understand the metes and bounds as defined in claims 5 and 7, which the applicants contest, claims 14 and 15 are clearly supported and described.

VII. REJECTION UNDER 35 U.S.C. §102(B)

Claims 5 and 7 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Drmanac *et al.*, for the reasons of record as stated in section 18 of the Office Action mailed August 30, 2007. Specifically, the Examiner alleges that because it is not clear what the boundaries of the PET domain are, that any eight amino acids would anticipate the claim. Applicants disagree.

As discussed above, the PET domain is not vague or indefinite, and the bounds of the domain are clearly set forth in the claims and as supported by the specification. Drmanac *et al.* does not teach or suggest a polypeptide fragment having at least eight amino acid residues and a PET domain as presently claimed.

Moreover, new claims 14 and 15, which are directed to polypeptides and polynucleotides in which the PET domain corresponds to position 19-89 of SEQ ID NO: 1 are clearly distinguishable over the disclosure of Drmanac *et al.*

Because Drmanac *et al.* does not teach a fragment having at least eight amino acids and a PET domain as presently claimed, Drmanac *et al.* cannot anticipate the claims as presently recited.

In light so the arguments presented above, and the claims as presently amended Applicants request that he Examiner withdraw the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,

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